

§ 82.1104

if such name contains the symbol “FD&C” such symbol shall be changed to “D&C”;

(2) The name of the basic radical combined in such color; and

(3) The word “Lake.”

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is “D&C Red No. 9—Barium Lake”, and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is “D&C Green No. 1—Aluminum Lake”.)

§ 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.1205 D&C Green No. 5.

The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205(a)(1) and (b)(2) of this chapter.

[47 FR 24285, June 4, 1982]

§ 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter. D&C Green No. 6 is restricted to use in externally applied drugs and cosmetics.

[47 FR 14147, Apr. 2, 1982, as amended at 51 FR 9785, Mar. 21, 1986]

§ 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254(a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

[42 FR 52396, Sept. 30, 1977]

§ 82.1255 D&C Orange No. 5.

(a) The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255(a)(1) and (b) of this chapter. D&C Orange No. 5 is restricted to the uses described in this section.

21 CFR Ch. I (4–1–02 Edition)

(b) The color additive D&C Orange No. 5 may be safely used for coloring externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug. The color additive D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products, and for coloring mouthwashes, dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

[49 FR 13343, Apr. 4, 1984]

§ 82.1260 D&C Orange No. 10.

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1261 D&C Orange No. 11.

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1306 D&C Red No. 6.

(a) The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

§ 82.1307 D&C Red No. 7.

(a) The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 7 may be safely used for coloring drugs

such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

§ 82.1317 D&C Red No. 17.

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a)(1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

§ 82.1321 D&C Red No. 21.

The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

§ 82.1322 D&C Red No. 22.

The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322 (a)(1) and (b) of this chapter.

[47 FR 53847, Nov. 30, 1982]

§ 82.1327 D&C Red No. 27.

The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 82.1328 D&C Red No. 28.

The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b) of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 82.1330 D&C Red No. 30.

The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b) of this chapter.

[47 FR 22511, May 25, 1982]

§ 82.1331 D&C Red No. 31.

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b) of this chapter. D&C Red No. 31 is restricted to use in externally applied drugs and cosmetics.

§ 82.1333 D&C Red No. 33.

(a) The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b) of this chapter.

(b) All lakes of D&C Red No. 33 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 33121, Aug. 30, 1988]

§ 82.1334 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azol-2-naphthalene-carboxylic acid.

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

§ 82.1336 D&C Red No. 36.

(a) The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b) of this chapter.

(b) All lakes of D&C Red No. 36 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 29031, Aug. 2, 1988]

§ 82.1602 D&C Violet No. 2.

The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b) of this chapter.

§ 82.1707 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

§ 82.1708 D&C Yellow No. 8.

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.